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REMARKS

Claims 1-4 are pending and under consideration in the above-identified application.

It is believed that the Office Action incorrectly indicates that the rejection is final. A final rejection in a first Office Action after a Request For Continued Examination has been filed with evidence of non-obviousness is inappropriate. Accordingly, Applicant will correctly presume that the rejection was non-final.

Claim Rejection Under 35 U.S.C. §103

Claims 1-4 stand rejected under 35 U.S.C. §103(a) over Kim et al. (U.S. Patent Application Publication No. 2002/0025951 or WO 01/47945) in view of Berge et al.

The rejection is clearly erroneous and totally contrary to established legal precedent. The Examiner has without reason deemed Applicant's evidence of non-obviousness to be unpersuasive and/or irrelevant.

An Examiner cannot legally choose to completely ignore evidence of non-obviousness. Rather, objective evidence of non-obviousness must be taken into account always. See for example *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986). Indeed, it is always error to exclude evidence of secondary indications from consideration. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983).

The Examiner apparently believes that there are at least some exceptions to these well established laws, which allow evidence to be deemed irrelevant, and/or to be deemed unpersuasive without sufficient analysis. Specifically, the Examiner has argued that evidence tending to show that it was not previously known how to make the claimed salts is not germane to patentability because the "salts would have been obvious to the skilled artisan in the art at the time of the present invention."

The Examiner appears to be arguing that evidence of non-obviousness is irrelevant to patentability when the invention would have been obvious under 35 U.S.C. §103(a). This is

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nonsensical. If evidence of non-obviousness is irrelevant to patentability under 35 U.S.C. §103, then when would it ever be relevant?

The Examiner's position is completely contrary to the relevant case law, all of which states that evidence of non-obviousness must be considered. In fact, MPEP Section 2141(V) states that "Office personnel should consider all rebuttal evidence that is timely presented by the Applicants when reevaluating any obviousness determination."

Applicant's evidence shows that it was not known, nor obvious, how to make the claimed salts, and that only after numerous failures and considerable trial and error did Applicant discover an unorthodox technique for forming the claimed salts. This evidence shows that the combined teachings of the prior art (Kim et al. in view of Berge et al.) did not make obvious a method for making the claimed salt forms. Nevertheless, the Examiner incorrectly believes that evidence showing that there was not any known method for making a claimed compound is irrelevant to patentability of the compound itself. This belief is completely contrary to the law. References relied upon to support a rejection for obviousness must provide an enabling disclosure. That is to say, the prior art reference relied upon must place the claimed invention in the possession of the public. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1550, 13 USPQ2d 1301, 304 (Fed. Cir. 1989).

The evidence shows that the combined teachings of Kim et al. in view of Berge et al. did not place the claimed salt forms in the possession of the public, and therefore were not enabling with respect to the claimed salt forms. Because the prior art references were not enabling with respect to the claimed salt forms, the applied references do not make the claimed salt forms obvious under 35 U.S.C. §103(a).

If a reference discloses only a hypothetical chemical structure, and does not enable its production, the Federal Circuit has indicated that the disclosure of the reference does not raise a question of obviousness. *In re Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). In the present case, the prior art references do not even disclose or suggest the claimed chemical structure, but rather disclose a multiplicity of 21-substituted progesterone derivatives (Kim et

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al.) and a multitude of different anions that had been used in the production of pharmaceutical salts (Berge et al.). Not only do the references fail to enable the claimed salt forms, which they must in order to make the claimed invention obvious under 35 U.S.C. §103, but they also fail to suggest or provide motivation for the specifically claimed salt forms.

The test of whether a particular compound described in the prior art may have been relied upon to show that the claimed subject matter at issue would have been obvious is whether the prior art provided an enabling disclosure with respect to the disclosed prior art compound. 776 F.2d at 297, 227 USPQ at 667, citing *In re Donohue*, 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985); *In re Hoeksema*, 399 F.2d 269, 273-74, 158 USPQ 596, 598-99 (C.C.P.A. 1968). Correctly applying the law, the claimed salt forms are patentable because the applied Kim et al. and Berge et al. references in combination do not provide an enabling disclosure with respect to the claimed salt forms.

Prior to Applicant's discovery of the claimed salt forms, such compounds were mere hypothetical structures in the sense that the prior art did not in fact enable the production of such compounds by a person of ordinary skill in the art.

It is respectfully submitted that upon proper consideration of the relevant law, it will be agreed that a claimed compound is not obvious under 35 U.S.C. §103(a) unless the prior art enables the person of ordinary skill in the art to make the compound. Neither Kim et al. nor Berge et al. teach anything about making the claimed salt forms. Applicant has submitted evidence showing that the claimed salt forms are not obvious, and were only made after considerable trial and error by an unorthodox technique, which is neither taught nor suggested by the prior art. For all of these reasons, it is respectfully submitted that the rejection should be withdrawn and the claims should be allowed.

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CONCLUSION

In view of the above amendments and remarks, it is respectfully submitted that the above-identified application is in condition for allowance and notice of the same is requested.

Respectfully submitted,

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Date

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/Gunther J. Evanina/

Gunther J. Evanina, Registration No. 35 502
Price, Heneveld, Cooper, Dewitt & Litton, LLP
695 Kenmoor, S.E.
Post Office Box 2567
Grand Rapids, Michigan 49501
(616) 949-9610